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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/520,052 | 09/26/2005 | Anna E Lobley | 04270/0202281-USO | 5082 |

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| EXAMINER | |
|---|---|
| STANDLEY, STEVEN H | |
| **ART UNIT** | **PAPER NUMBER** |
| 1649 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/520,052 | LOBLEY ET AL. | |
| | Examiner | Art Unit | |
| | Steven H. Standley | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Election/Restrictions***

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-12, 38 (in part), 39 (in party), 41 (in part), drawn to a Serotonin receptor of SEQ ID NO: 2.

Group 2, claim(s) 13-14, drawn to a fusion protein.

Group 3, Claims 16-18, 38 (in part), 39 (in part), and 41 (in part), and 47-48, drawn to a nucleic acid encoding a fragment of the serotonin receptor shown in SEQ ID NO: 1.

Group 4, Claims 19, 38 (in part), and 41 (in part) drawn to a host cell transformed with a vector containing SEQ ID NO: 1.

Group 5, Claims 20-22, and 38 (in part) and 41 (in part) drawn to ligand that binds to a serotonin receptor.

Group 6, Claim 23-25 and 38 (in part) and 41 (in part) drawn to a compound that changes the expression of the receptor.

Groups 7, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is nausea or vomiting.

Groups 8, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is pain.

Groups 9, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is eating disorders.

Groups 10, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is alcoholism.

Groups 12, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is psychosis.

Groups 13 Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is side effects of cancer therapies.

Groups 14, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is irritable bowel syndrome.

Groups 15, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is gastrointestinal disorders.

Groups 16, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is Alzheimer's disease.

Groups 17, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is Parkinson's disease.

Groups 18, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is Huntington's disease.

Groups 19, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is Alzheimer's disease.

Groups 20, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is a cognitive disorder.

Groups 21, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is a behavioural disorder.

Groups 22, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is phobia.

Groups 23, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is an anxiety related illness.

Groups 24, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is addiction.

Groups 25, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is obsessive compulsive disorder.

Groups 26, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is memory and learning disorder.

Groups 27, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is depression.

Groups 28 Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is asthma.

Groups 29, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is inflammation.

Groups 30 Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is sexual dysfunction.

Groups 31, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is a neuroendocrine disorder.

Groups 32, Claims 27-35 (in part) as it relates to a method of detecting a disease in a patient wherein the disease is a cardiovascular disorder.

Groups 33, Claims 27-34, and 36-37 as it relates to a method of detecting a disease in a patient wherein the disease is a T-cell disease such as HIV.

Groups 34, Claims 42-44 (in part) as it relates to a method of treating a disease by administration of protein of claim 1.

Groups 35, Claims 42-44 (in part) as it relates to a method of treating a disease by administration of nucleic acid.

Groups 36, Claims 42-44 (in part) as it relates to a method of treating a disease by administration of vector.

Groups 37, Claims 42-44 (in part) as it relates to a method of treating a disease by administration of a host cell.

Groups 38, Claims 42-44 (in part) as it relates to a method of treating a disease by administration of a ligand.

Groups 39, Claims 42-44 (in part) as it relates to a method of treating a disease by administration of a compound.

Groups 40, Claims 45 (in part) as it relates to a method of monitoring the therapeutic treatment of disease in a patient by measuring polypeptide.

Groups 41, Claims 45 (in part) as it relates to a method of monitoring the therapeutic treatment of disease in a patient by measuring nucleic acid.

Groups 42, Claims 46 (in part) as it relates to a method of identifying a compound that is effective in the treatment of a disease using the polypeptide.

Groups 43, Claims 46 (in part) as it relates to a method of identifying a compound that is effective in the detection of a disease using the polypeptide.

Groups 44, Claims 46 (in part) as it relates to a method of identifying a compound that is effective in the treatment of a disease using the nucleic acid.

Groups 45, Claims 46 (in part) as it relates to a method of identifying a compound that is effective in the detection of a disease using the nucleic acid.

Groups 46, Claims 49 as it relates to a kit containing a microarray.

Groups 47, Claims 50 as it relates to a kit containing antibodies.

Groups 48, Claims 51 as it relates to a transgenic knockout non-human mammal.

Groups 49, Claims 52 as it relates to a method of screening using the transgenic knockout non-human mammal.

2. This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. The inventions listed as Groups I-55 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Xiao et al (US patent publication number 20040023876 with priority to filed 10/2000) teaches claim 1 (which recites SEQ ID NO: 2) by disclosing a sequence with 100% identity to that of SEQ ID NO: 2. (See Xiao et al. Figure 5). Therefore claim 1-12 lack a special technical feature in common with claims 13-52 and cannot share one with the other claims.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Stucker can be reached on **(571) 272-0911**.

The fax number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
1/02/07

/David Romeo/

Primary Examiner, Art Unit 1647